CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Tryptyr**
Generic Name	acoltremon
Company	Alcon Labs
Date of FDA Approval	May 28, 2025
Indication	To treat the **signs and symptoms of dry eye disease**

OVERALL GRADE

B

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	11.2%	50	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	74.8%	350	Increased	**A**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	13.9%	70	Similar	**B**
Asian	6.3%	8.5%	40	Increased	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	11.8%	47	Increased	**D**

References: Phase 3 pivotal trials: COMET-2 [NCT-05285644] and COMET-3 [NCT-05360966]; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/217370Orig1s000IntegratedR.pdf pgs 21,22, 32; doi:10.1001/jamaophthalmol.2022.4394; doi: 10.1016/j.ajo.2011.02.026; https://www.ajo.com/action/showPdf?pii=S0002-9394%2817%2930290-8; DOI: 10.1016/s0002-9394(03)00218-6; No PMR/PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Emrelis**
Generic Name	telisotuzumab vedotin-tllv
Company	Abbvie
Date of FDA Approval	May 14, 2025
Indication	To treat **locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression after prior systemic therapy**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	50.0%	84	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	30.4%	51	Similar	**C**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.8%	3	Similar	**D**
Asian	6.3%	32.7%	55	Decreased	**A**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	0.6%	1	Decreased	**C**

References: Phase 3 pivotal trial Luminosity M14-239 ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761384Orig1s000MultidisciplineR.pdf pgs 96-97; doi: 10.1177/17588359241279715; https://doi.org/10.1186/s12885-024-12126-8; https://www.ncbi.nlm.nih.gov/books/NBK519578/#:~:text=Lung%20adenocarcinoma%20is%20the%20most,patients%20affected%20by%20lung%20adenocarcinoma.; No PMR/PMC

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Avmapki Fakzynja Co-Pack**
Generic Name	avutometinib and defactinib
Company	VERASTEM INC
Date of FDA Approval	May 8, 2025
Indication	To treat **KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC) after prior systemic therapy (orphan)**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	28.7%	33	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	100%	115	Increased	**NA**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	4.3%	5	Decreased	**C**
Asian	6.3%	3.5%	4	Decreased	**C**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	2.2%	3	Similar	**D**

References: Phase 3 pivotal trial RAMP-201; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219616Orig1s000MultidisciplineR.pdf pgs 173,175; https://seer.cancer.gov/statfacts/html/ovary.html; https://gis.cdc.gov/Cancer/USCS/#/explore/incidence; No PMR/PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Imaavy**
Generic Name	nipocalimab-aahu
Company	JANSSEN BIOTECH
Date of FDA Approval	April 29, 2025
Indication	To treat **generalized myasthenia gravis (orphan)**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	24.2%	18	Increased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	60.1%	50	Increased	**C**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.3%	1	Increased	**F**
Asian	6.3%	32.0%	24	Similar	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	7.8%	8	Decreased	**C**

References: Phase 3 pivotal trial 011; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761430Orig1s000IntegratedR.pdf pgs 47-48; https://doi.org/10.1212/WNL.0000000000202945; doi: 10.3389/fneur.2024.1339167; doi: 10.3390/jcm10112235; https://www.rarediseaseadvisor.com/disease-info-pages/myasthenia-gravisepidemiology/; https://rarediseases.org/rare-diseases/myasthenia-gravis/#affected; No PMR/PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**penpulimab-kcqx**
Generic Name	penpulimab-kcqx
Company	AKESO BIOPHARMA
Date of FDA Approval	April 23, 2025
Indication	To treat adults with **non-keratinizing nasopharyngeal carcinoma** (orphan)

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	5.0%	16	Similar	**D**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	20.4%	56	Decreased	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	0.2%	0	Similar	**D**
Asian	6.3%	98.3%	270	Increased	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	1.0%	2	Decreased	**C**

References: Phase 3 pivotal trials AK105-304, AK105-202; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761258Orig1s000MultidisciplineR.pdf pgs 95,99,131, 220; PMID: 37227924 DOI: 10.34067/KID.0000000000000165; doi: 10.1016/j.ekir.2023.02.1086 PMCID: PMC10166729; PMID: 37180506; DOI: 10.1159/000541869; PMID: 35757475; doi:10.1001/archotol.132.10.1035 PMC for demographic subgroups that are reflective of the U.S. patient population

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Vanrafia**
Generic Name	atrasentan
Company	Novartis
Date of FDA Approval	April 2, 2025
Indication	To **reduce proteinuria in adults with primary IgA nephropathy at risk of rapid disease progression**

OVERALL GRADE

B

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	6.3%	11	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	41.1%	54	Decreased	**A**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.9%	4	Decreased	**C**
Asian	6.3%	57.0%	75	Increased	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	20.7%	32	Similar	**B**

References: Phase 3 pivotal trial ALIGN; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219208Orig1s000IntegratedR.pdf pgs 36-37; PMID: 37227924 DOI: 10.34067/KID.0000000000000165; doi: 10.1016/j.ekir.2023.02.1086 PMCID: PMC10166729; PMID: 37180506; DOI: 10.1159/000541869; No PMR/PMC

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Qfitlia**
Generic Name	fitusiran
Company	Genzyme
Date of FDA Approval	March 28, 2025
Indication	To **prevent or reduce the frequency of bleeding episodes in hemophilia A or B (orphan)**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	1.0%	3	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	NA	NA	NA	**NA**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.1%	3	Decreased	**C**
Asian	6.3%	62.1%	169	Decreased	**A**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	4.0%	5	Similar	**D**

References: Phase 3 pivotal trials ATLAS-INH (EFC14768), ATLAS-A/B (EFC14769); DOI: 10.1111/hae.13998 ; DOI: 10.1182/asheducation-2010.1.191; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219019Orig1s000IntegratedR.pdf pgs. 49, 53, 62, 100, 252 ; No PMR/PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Blujepa**
Generic Name	gepotidacin
Company	GSK
Date of FDA Approval	March 25, 2025
Indication	To treat **uncomplicated urinary tract infections**

OVERALL GRADE

A

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	23.3%	353	Increased	**A**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	100%	1,572	Increased	**A**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	6.9%	114	Similar	**C**
Asian	6.3%	5.1%	74	Similar	**B**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	32.7%	524	Similar	**A**

References: Phase 3 pivotal trials EAGLE-2, EAGLE-3; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/218230Orig1s000IntegratedR.pdf pg 23, 50; doi: 10.1177/1756287219832172; https://www.ncbi.nlm.nih.gov/books/NBK470195/; No PMR/PMC

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Romvimza**
Generic Name	vimseltinib
Company	DECIPHERA PHARMS
Date of FDA Approval	February 14, 2025
Indication	To treat **symptomatic tenosynovial giant cell tumor**

OVERALL GRADE

D

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	9.8%	5	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	59.3%	46	Increased	**C**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	3.3%	4	Unknown	**D**
Asian	6.3%	4.1%	1	Increased	**D**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	3.3%	3	Unknown	**D**

References: Pivotal Phase 3 trial DCC-3014-03-001 MOTION; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219304Orig1s000MultidisciplineR.pdf pg 132; https://rarediseases.org/rare-diseases/tenosynovial-giant-cell-tumor/#affected; DOI: 10.1016/j.ctrv.2022.102491; DOI: 10.1038/srep36332; No PMR/PMC

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Clinical Trial Demographic Scorecard

Drug	
Tradename	**Gomekli**
Generic Name	mirdametinib
Company	SPRINGWORKS
Date of FDA Approval	February 11, 2025
Indication	To treat **neurofibromatosis type 1 (orphan)**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	1.8%	2	Decreased	**C**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	58.8%	67	Similar	**B**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	14.0%	16	Similar	**C**
Asian	6.3%	3.5%	4	Similar	**D**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	7.9%	9	Similar	**D**

References: Pivotal Phase 3 trial MEK-NF-201 ReNeu ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219379Orig1s000,219389Orig1s000MultidisciplineR.pdf pg 150;
https://rarediseases.org/rare-diseases/neurofibromatosis-type-1-nf1/#affected; DOI: 10.3928/01913913-20190321-02;
https://nfpittsburgh.org/whatisnf/facts-statistics/; No PMR/PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Journavx**
Generic Name	suzetrigine
Company	Vertex
Date of FDA Approval	January 30, 2025
Indication	To treat **moderate to severe acute pain**

OVERALL GRADE

B

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	4.8%	47	Increased	**D**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	91.7%	803	Increased	**A**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	25.5%	239	Increased	**B**
Asian	6.3%	1.8%	16	Decreased	**C**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	34.0%	281	Increased	**B**

References: Pivotal Phase 3 trials VX22-548-104, VX22-548-105 ; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/219209Orig1s000IntegratedR.pdf pgs 26,27,33; doi: 10.7861/clinmed.22.4.ac-p; PMID: 26526704; https://doi.org/10.1111/pme.12528; PMID: 35260338; PMID: 25422152; No PMR/PMC

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Grafapex**
Generic Name	treosulfan
Company	MEDEXUS
Date of FDA Approval	January 21, 2025
Indication	For use **in allogeneic hematopoietic stem cell transplantation for AML and MDS (orphan)**

OVERALL GRADE

C

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	26.0%	76	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	39.1%	109	Decreased	**A**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	NR	NR	Decreased	**C**
Asian	6.3%	NR	NR	Decreased	**C**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	NR	NR	Decreased	**C**

References: Pivotal Phase 3 trial MC-FludT.14/L Trial II; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/214759Orig1s000MultidisciplineR.pdf pg 37; https://seer.cancer.gov/statfacts/html/amyl.html; https://seer.cancer.gov/statistics-network/explorer/application.html?site=409&data_type=1&graph_type=10&compareBy=sex&chk_sex_3=3&chk_sex_2=2&series=9&race=8&age_range=1&hdn_stage=101&advopt_precision=1&advopt_show_ci=on&hdn_view=0; PMC for race and ethnicity

CARER Group

Clinical Trial Demographic Scorecard

Drug	
Tradename	**Datroway**
Generic Name	datopotamab deruxtecan-dlnk
Company	DAIICHI SANKYO INC
Date of FDA Approval	January 17, 2025
Indication	To treat unresectable or metastatic, **HR-positive, HER2-negative breast cancer**

OVERALL GRADE

B

Age

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	17.3%	22.3%	91	Increased	**B**

Sex

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.4%	98.8%	360	Increased	**NA**

Race

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.6%	1.5%	4	Decreased	**C**
Asian	6.3%	40.7%	146	Decreased	**A**

Ethnicity

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	19.1%	11.3%	40	Decreased	**B**

References: Pivotal Phase 3 trial TROPION-Breast01; https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761394Orig1s000MultidisciplineR.pdf pgs 135-6; https://seer.cancer.gov/statfacts/html/breast-subtypes.html; PMID: 36895447; PMC for race and ethnicity